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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,468	10/18/2001	Lorenzo De Ferra	0558-4017	7031

7590 01/28/2002

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EXAMINER


MURRAY, JOSEPH H

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 01/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>09/982,468</b>	Applicant(s) <b>De Ferra et al</b>	
	Examiner <b>Joseph Murray</b>	Art Unit <b>1626</b>	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☐ Responsive to communication(s) filed on \_\_\_\_\_

2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1-15 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some\* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other: \_\_\_\_\_

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Claims 1-15 are pending in the instant application.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Although the specification teaches preferred hydrocarbon solvents and preferred polar organic solvents it does not enable the claim that all hydrocarbon solvents and polar organic solvents would work in the instantly claimed purification process as described in claim 1.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 line 10 "hydrocarbon solvent" and "polar organic solvent" is unclear. It is not clear which solvents or group of solvents applicant is claiming, e.g. aromatic solvents and/or

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aliphatic solvents with 6-9 carbon atoms etc. There is no support that all organic hydrocarbon solvents or polar organic solvents would work in the instant process. The combining of claims 1, 2 and 5 would obviate this rejection

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation "where the serine portion is in D, L, or racemic form", and the claim also recites "and preferably in L form" which is the narrower statement of the range/limitation.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by De Ferra et al, USPN 5700668.

The instant application claims a process for the purification of phosphatidylserines of the formula I by the extraction of the phosphatides in a hydrocarbon solvent with a mixture of water and a polar organic solvent.

The prior art reference also teaches a process for the purification of phosphatidylserines from the trans-esterification reaction in toluene, a hydrocarbon solvent, and water and methanol, polar organic solvents, see examples 2-4 columns 5 and 6.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Ferra et al, USPN 5700668.

The instant application claims a process for the purification of phosphatidylserines of the formula I by the extraction of the phosphatides in a hydrocarbon solvent with a mixture of water

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and a polar organic solvent, where the hydrocarbon is selected from toluene, xylene, heptane, hexane, and cyclohexane, and the polar organic solvent is an alcohol, where specific preference is given to isopropanol.

The De Ferra et al reference teaches a process for the production of phosphatidylserines from phosphatidylcholines via trans-esterification reaction and the purification of the phosphatidylserine in toluene solution, which is separated from an aqueous phase and then reduced and dissolved in heptane and methanol, which is separated and concentrated to produce 97% phosphatidylserine, see examples 2-4 columns 5 and 6.

The prior art, however, does not specifically indicate that isopropanol may be used as the alcohol of choice rather than methanol, although one of ordinary skill in the art would have been motivated to employ isopropanol, or any other lower alcohol, in the extraction process since this is merely a matter of choice of the practicing chemist, and given the fact that the partition differences between the lower alcohols is negligible.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the various lower alcohols in the extraction process since this is a matter of choice of the practicing chemist and since the variation in the partition between the alcohols is negligible. Further, the prior art reference teaches the standard extraction process of a reaction product, and it is well known to the practicing chemist that variations in the extraction process are expected in order to optimize the results.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Joseph Murray whose telephone number is (703) 308-4540.

The examiner can normally be reached on Monday-Friday from 6:30 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-2286.

A handwritten signature in black ink, appearing to read 'Solola', with a horizontal line drawn underneath it.

Taofiq Solola  
Primary Patent Examiner  
GAU 1626

Joseph Murray  
January 23, 2002